DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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JUN 30 2005

Mr. Monte R. Browder
IVAX Pharmaceuticals, Inc.
4400 Biscayne Boulevard
Miami, Florida 33137

Re: Docket No. 2005P-0008/CP1

Dear Mr. Browder:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on January 6, 2005. Your petition requests that the Agency recognize 180-day exclusivity for IVAX's ANDA No. 76-052 for simvastatin tablets (5, 10, 20 and 40 mg.), and reinstate listings for U.S. Patent Nos. RE 36481 and RE 36520 in the *List of Approved Drug Products with Therapeutic Equivalence Evaluations*, which is generally known as the "Orange Book."

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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